OCT 21 2009

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: k093116.

The purpose of this 510(k) submission is to provide additional Analytical Reactivity information for the currently 510(k) cleared RAMP® Influenza A/B Assay (k071591).

Establishment:

Response Biomedical Corporation
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Contact: Ken Pilgrim
Director – Quality / Regulatory

Prepared: 16 October 2009

Regulatory Information:

Trade Name:	RAMP® Influenza A/B Assay
Common Name:	Influenza A/B immunological test system
Classification Name:	Influenza A/B immunological test system
Regulation Number:	866.3330, Influenza virus serological reagents
Classification:	Class I
Product Code:	GNX
Panel:	Microbiology

Predicate Device:

Immunoassay:	RAMP® Influenza A/B Assay, k071591

Intended Use

The RAMP® Influenza A/B Assay is a qualitative immunochromatographic assay used to identify the presence of Influenza A and Influenza B nucleoprotein antigens in nasal wash, nasal aspirate, nasopharyngeal aspirate, and nasopharyngeal swab specimens from symptomatic patients. It is an in vitro diagnostic assay that aids in the rapid differential diagnosis of influenza viral infections in symptomatic patients. A negative test is presumptive and it is recommended these results be confirmed by cell culture. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions.

The test performance characteristics for Influenza B were established primarily with retrospective, frozen specimens. Users may wish to further evaluate the sensitivity performance of this test for Influenza B using fresh samples.

RAMP Description of the Device:

The RAMP Influenza A/B Assay is a qualitative immunochromatographic test that utilizes the RAMP 200 instrument for the differential determination of Influenza A and Influenza B in nasal wash/aspirate, nasopharyngeal aspirate, and nasopharyngeal swab samples. A wash/aspirate or swab sample is mixed with Sample buffer and applied into the sample well of the Test Cartridge. The sample migrates along the strip. Fluorescent-dyed latex (test) particles, coated with anti-Influenza A and anti-Influenza B antibodies bind to Influenza A or B antigens, respectively, if present in the sample. As the sample migrates along the strip, Influenza-bound particles are captured at either the Influenza A or the Influenza B detection zone, and additional particles are captured at the internal standard zone.

The instrument then measures the amount of fluorescence emitted by the complexes at the two detection zones (Influenza A and Influenza B) and at the internal standard zone. The instrument calculates a ratio (RAMP Ratio) using the fluorescence reading of each detection zone (A or B) and the internal standard zone. The instrument compares these ratios to pre-defined threshold limits to determine a positive or negative result for Influenza A and Influenza B in the tested sample.

Comparison of Technological Characteristics:

Characteristic	Predicate RAMP Influenza A/B Assay (k071591)	RAMP Influenza A/B Assay Additional Analytical Sensitivity (k093116)
Intended Use	The RAMP® Influenza A/B Assay is a qualitative immunochromatographic assay used to identify the presence of Influenza A and Influenza B nucleoprotein antigens in nasal wash, nasal aspirate, nasopharyngeal aspirate, and nasopharyngeal swab specimens from symptomatic patients. It is an in vitro diagnostic assay that aids in the rapid differential diagnosis of influenza viral infections in symptomatic patients. A negative test is presumptive and it is recommended these results be confirmed by cell culture. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions.	Same
Assay Type	Qualitative for differential determination of Influenza A and Influenza B	Same
Test Methodology	Rapid immunochromatographic tests used for the detection of influenza virus antigen utilizing antibodies targeted toward the nucleoprotein (NP) of the virus and thus do not require viable virus particles for detection.	Same

Characteristic	Predicate RAMP Influenza A/B Assay (k071591)	RAMP Influenza A/B Assay Additional Analytical Sensitivity (k093116)
Sample Type	Nasal wash/aspirate, nasopharyngeal aspirate, and nasopharyngeal swab	Same

Summary of Studies:

ANALYTICAL PERFORMANCE CHARACTERISTICS

Analytical Reactivity

The RAMP Influenza A/B Assay was evaluated for analytical reactivity by testing an isolate strain of Influenza A (Swine NY/02/2009) prepared in Copan UTM. The isolate was tested at different dilutions to find the lowest concentration that would consistently give positive results. Five (5) replicates were tested at each concentration. The reactivity for Influenza A/Swine NY/02/2009 was determined to be $1.0x10^2$ $TCID_{50}$/mL.

Titer tested (TCID50/mL)	Flu A Result	Flu B Result
1×10^5	5/5 Pos	5/5 Neg
1×10^4	5/5 Pos	5/5 Neg
1×10^3	5/5 Pos	5/5 Neg
1×10^2	5/5 Pos	5/5 Neg
1×10^1	5/5 Neg	5/5 Neg

Although the RAMP Influenza A/B Assay has been shown to detect the 2009 H1N1 influenza virus in one culture isolate, the performance characteristics of this device with clinical specimens that are positive for the 2009 H1N1 influenza virus have not been established. The RAMP Influenza A/B Assay can distinguish between influenza A and B viruses, but it cannot differentiate influenza subtypes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

OCT 21 2009

Ken L. Pilgrim, P.Eng.
Director, Quality / Regulatory
Response Biomedical Corporation
1781 - 75th Avenue W.
Vancouver, BC V6P 6P2

Re: k093116
Trade/Device Name: RAMP Influenza A/B Assay
Regulation Number: 21 CFR 866.3330
Regulation Name: Influenza Virus Serological Reagents
Regulatory Class: Class I
Product Code: GNX
Dated: September 30, 2009
Received: October 2, 2009

Dear Mr. Pilgrim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of

substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, Ph.D.
Director, Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

Indications for Use

510(k) Number (if known): 093116

Device Name: RAMP® Influenza A/B Assay

Indications for Use:

The RAMP® Influenza A/B Assay is a qualitative immunochromatographic assay used to identify the presence of Influenza A and Influenza B nucleoprotein antigens in nasal wash, nasal aspirate, nasopharyngeal aspirate, and nasopharyngeal swab specimens from symptomatic patients. It is an in vitro diagnostic assay that aids in the rapid differential diagnosis of influenza viral infections in symptomatic patients. A negative test is presumptive and it is recommended these results be confirmed by cell culture. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions.

The test performance characteristics for Influenza B were established primarily with retrospective, frozen specimens. Users may wish to further evaluate the sensitivity performance of this test for Influenza B using fresh samples.

Prescription Use X (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Uwe Scherf

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k093116